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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,014	07/31/2003	Christopher J. Calhoun	MA9606P	9368

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EXAMINER	
SOROUSH, ALI	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,014	CALHOUN ET AL.	
	Examiner	Art Unit	
	Ali Soroush	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *30-33 and 37-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restricions

Applicant's election without traverse of Group I (claims 1-29 and 34-36) in the reply filed on October 06, 2006 is acknowledged.

Claim Objections

Claims 34-36 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite dependency on a method claim. The independent claim however is an apparatus claim and therefore the dependent claims 34-36 are improper.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language.

Claims 1-29 recite the term "substantially" rendering the claims indefinite in that it fails to point out the metes and bounds of certain aspects of the claims such as "exposed surfaces", "non-porous", and "smooth side". The term "substantially" makes

unclear for example how much of the implant surface may remain exposed or how much texture if any at all would be acceptable on the membrane.

Claims 34-36 recite dependency on a method claim. The independent claim however is an apparatus claim therefore the claims fail to have antecedent basis for the statement "the method according to claim 33".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 14-17, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Arm et al (WO 93/20859, published 10/28/1993).

Arm et al. teaches, "biodegradable films comprising a polylactic/polygylcolic acid copolymer, a therapeutically effective amount of polypeptide growth factor, and a carrier are provided." (See abstract). "Compositions are in the form of biodegradable polyester films, such as polylactic acid, polyglycolic acid ..." (See page 5, Lines 12-13). "Because polymers of enantiomeric lactides are crystalline and therefore more resistant to degradation than their racemic counterparts, it is preferred to used mixed enantiomer

(e.g. poly (D, L-lactide acid)) polymers within the present invention." (See page 6, Lines 19-23). "Film thickness of less than about 50 μm are preferred, particularly film thickness between 5 and 20 μm." (See page 6, Lines 33-35). "The films may be affixed to the outer surface of an implantable or prosthetic device such as a screw, pin, plate, rod or artificial joint component." (See abstract). Arm et al. teaches the use of the film with non-biological implants such as a medical device, i.e. "rods" for "enhancing bone repair of bone fractures" (see abstract) and also with biological implants such as an allograft material, i.e. "demineralized bone matrix plugs" to induce new bone formation. "The films may, for example, be wrapped around the outer surfaces of surgical screws, rods, pins, plates, and the like. The films can also be used to coat bone filling materials, such as hydroxyapetite blocks, demineralized bone matrix plugs, collagen matrices and the like ..." (See page 13, Lines 9-19). In regards to resorbablity of the film Arm et al. teaches, "the unloaded *in vitro* degradation study showed mass loss from 50:50 and 85:15 PLA/PGA copolymer rods in the range of 80-95% by the 76-day point ..." (See page 15, Lines 25-27). In regards to the film characteristic being nonporous although Arm et al. is silent to this because the film has the same characteristic composition therefore products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. Therefore, it would naturally be assumed that the film taught by Arm et al. would be nonporous. In regards to the "substantially smooth"

side characteristic the applicant fails to particularly and clearly delimit the metes and bounds of the term "substantially".

Claims 1, 4, 7, 13-23, 25, and 29 rejected under 35 U.S.C. 102(e) as being anticipated by Lahtinen (US 2003/0059463 A1, published 3/27/2003).

Lahtinen teaches, "the invention relates to a medical device suitable for implantation into a human or animal, such as an implantable prosthetic device, a method of improving a human or animal body's acceptance of a medical device comprising at least one synthetic surface as well as a method of producing a device according to the invention." (See column 1, paragraph 1). "Said device comprises a core and a nucleic acid present in a biologically compatible medium ..." (See column 6, paragraph 21). "The biologically compatible medium is a biostable polymer, a biosorbable polymer, a biomolecule, a hydrogel polymer or fibrin." (See column 7, paragraph 24). "Biosorbable polymers that may be used include, but are not limited to, poly-(L-lactic acid), ... poly(D,L-lactic acid) ...." (See column 26, paragraph 112). Lahtinen further teaches, "In one aspect there is a solid/solid solution of polymer and drug. This means that the drug and the polymer both are soluble in the same solvent and have intimately admixed in the presence of that solvent. The drug and polymer can be applied in various ways, such as by simply immersing the implant into the solution or by spraying the solution onto the implant. The polymer can be porous or nonporous on the implant" (See column 27, paragraph 112). Lahtinen teaches that the implant to be "immersed or sprayed" with the solution can be an implant such as an "organ", allografting material such as a "vascular graft" to be implanted in soft tissue, or a

prosthesis such as a "pacemaker lead" or "cardiac assist device" to be implanted in soft tissue. "A medical implant maybe an implantable prosthetic device, and more particularly, a cardiovascular implant or tissue implant, as well as blood-contacting medical implant, a tissue contacting medical implant, a bodily fluid-contacting medical implant, an implantable medical device, an extracorporeal medical device, an artificial heart, a cardiac assist device, an endoprosthesis medical device, a vascular graft, a stent graft, a heart valve, a cardiovascular patch, a temporary intravascular implant, an annuloplasty ring, a catheter, a pacemaker lead, a biosensor, a chamber for holding living cells, an organ implant, or a bioartificial organ." (See column 8, paragraph 35). "Preferred devices are implantable in the body, and include cardiovascular implants, tissue implants, artificial organs, such as pancreas, liver, and kidney, and organ implants, such as breast, penis, skin, nose, ear, and orthopedic implants" (See column 23, paragraph 129).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 7-18, 21, 22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hossainy et al. (US 6541373, published 09/17/2002).

Applicant Claims

Applicant claims a method for attenuating adhesion between an implant and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide surrounding a biological or non-biological implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Hossainy et al teaches, a "method of forming a therapeutic coating onto a surface of an implantable prosthesis" (See title). Examples of implantable devices

"include self-expandable stents, balloon-expandable stents, and grafts, among other possibilities". (See column 3, Lines 39-40). An example of a graft taught by Hossainy et al. is a vascular graft. (See column 4, Line 12). "The graft may be attached at each end of the diseased region ... alternatively the diseased region maybe removed and replaced by the graft." Hossainy et al. further teaches, " In accordance with some embodiments, a predetermined amount of therapeutic substance is added to predetermined amount of first fluid." (See column 3, Lines 64-66). "Exemplary first fluids include, but are not limited to, deionized water, methanol, ethanol, freon, and acetonitrile. In some other embodiments, the composition additionally includes a polymer, or combination of polymers, dissolved in the first fluid. Example of biosorbable materials include but are not limited to polycaprolactone (PCL), poly-D,L-lactide, poly-L-lactic acid (L-PLA) ..." (See column 5 Lines 46-62). "In such embodiments, the polymeric materials can make up from about 0.1% to about 30%, or more particularly from about 0.1% to about 10% by weight of the total weight of the composition..." (See column 6, Lines 14-16). An example method of coating a implantable prosthesis is taught by Hosseiny et al. "A ... ethylene vinyl alcohol copolymer:DMSO solution is made ... Actinomycin is added to the EVOH:DMSO solution to form a suspension. Pluronic, a suspension stabilizer is added to the suspension ... The ... stent is attached to mandrel wires and dipped into the suspension. The coated stent is then placed in a vacuum oven ..." (See column 11, Lines 39-55). Following application of the composition to the prosthesis removal of the first fluid techniques such as "evaporation at ambient pressure and room temperature in an anhydrous atmosphere for 48 hours, or exposure to mild

heat, e.g. 60-65°C, under vacuum conditions" is used (column 8, Lines 4-7). In variations of the application of the composition to the surface of the prosthesis Hossainy et al. teaches, "spraying the composition onto the prosthesis or immersing the prosthesis in the composition." (See column 7, Lines 48-49).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Hossainy et al. does not anticipate the instant invention but they do teach a class of polymers from which polylactic acid and more specifically poly-L-lactic acid and poly-D, L-lactic acid can be elected. Further, Hossainy et al. teaches a class of first fluids (solvents) from which acetonitrile can be elected. Hossainy et al. thereby teaches the combination of the polymer and solvent of the instant invention. Although a drying step using a vacuum oven is not anticipated by Hossainy et al. the teaching of EVOH:DMSO would lead one skilled in art to use the same method steps of coating an implant and drying using a vacuum oven with a solution of polylactic acid: acetonitrile.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

In the example method taught by Hossainy et al. for coating an implantable prosthesis the EVOH could be replaced with a lactic polymer as this is given as a suitable substitute polymer and DMSO can be replaced with acetonitrile as Hossainy et al give this as suitable first fluid substitute. Therefore, any combination of polymer to first fluid (solvent) composition disclosed in Hossainy et al. can reasonably be dried using a vacuum oven or under anhydrous atmosphere, room temperature conditions. An anhydrous atmosphere being simply air with the moisture removed would make

obvious the use of both evaporation techniques concurrently. Since, both drying by air and vacuum oven cause the solvent to evaporate from the composition after the composition is applied to the implant the combination of both techniques would be obvious because it would enhance the evaporation of the solvent. One would be motivated to use polylactides because a polylactide such as poly-D,L-lactide is more available to degradation.

Claims 1-6 and 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ledergerber et al. (US 4955907, published 09/11/1990) in view of Calhoun et al. (US 2002/0001609 A1, published 01/3/2002).

Applicant Claims

Applicant claims a method for attenuating adhesion between an implant and surrounding tissue providing a non-porous, resorbable planar membrane polymer of poly-L-lactide and poly-D-L-lactide surrounding a biological or non-biological implant.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Ledergerber teaches, "the present invention is directed to: (A) the use of a covering for a prosthesis which has high tissue in-growth, biocompatibility , low reactivity and scar tissue formation and which disorganizes scar tissue that does form ... Expanded PTFE (polytetrafluroethylene) is used in the preferred embodiment of this invention." (See column 2, Lines 66-68 and column 3, Lines 1-4). "Implantable prosthetic devices have been used in numerous locations in the body. The most common breast prosthesis is ... in which there is an elastomeric container, typically

silicone, which is filled with soft gel, typically silicone gel or a saline solution or combination of both. It is known that when a prosthetic device ... is implanted in the body (see column 1, Line 10), the fibrous scar tissue encapsulates the device." (See column 1, Lines 12-25). Ledergerber further teaches that PTFE is "available in sheet form of various thicknesses ..." (See column 7, Lines 1-2). Ledergerber also teaches that PTFE maybe applied to the prosthesis by a complex expandable weave. (See column 7, Lines 17-23).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Ledergerber lacks the teaching of a planar poly-L-lactide and poly-D-L-lactide polymer membrane that is resorbable in less than 24 months from initial implantation of the implant into the patient. Also, Ledergerber lacks a teaching of heat-shrinking the membrane around the implant. These deficiencies are cured by the teachings in Calhoun et al.

Calhoun et al. teaches, "a resorbable polylactide polymer scar tissue reduction barrier membrane." (See abstract). Calhoun et al further teaches, " A resorbable scar-tissue reduction micro-membrane for attenuating a formation of post-surgical scar tissue between a healing post-surgical site and adjacent surrounding tissue following an in vivo surgical procedure ... the implant comprising: a substantially planar membrane of resorbable polymer base material having a first substantially-smooth side and a second substantially-smooth side, the substantially planar membrane of resorbable polymer

base material comprising a single layer of resorbable polymer base material ... wherein the thickness of the single layer of resorbable polymer base material ... is between about 10 microns and about 300 microns; wherein the single layer of resorbable polymer base material is nonporous; and wherein the single layer of resorbable polymer base material consists essentially of a material selected from the group consisting of : poly-lactide polymer; and a copolymer of two or more poly-lactides; and ... is adapted to be resorbed into the mammalian body within a period of approximately 18 to 24 months from initial implantation of the implant into the mammalian body." (see claim 1). "Wherein the resorbable polymer base material is 70:30 poly(L-lactide-co-D,L-lactide)."(See claim 2). Calhoun et al. further teaches, "In yet another embodiment, the scar-reduction resorbable barrier micromembrane can be heat bonded or sealed directly to itself in an application, for example, wherein the micromembrane is wrapped around a structure and then heat joined to itself." (See column 7, Paragraph 49).

It is noted that Calhoun et al. is commonly owned by the assignee of the instant application but has a different inventive entity. The date of the publication of Calhoun et al. makes this acceptable under 35 U.S.C. 102(a) date as art in relation to the earliest priority date of the instant application and therefore can be used as art under 35 U.S.C 103(a) rejection.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the invention to use the micromembrane of Calhoun et al. with the prosthesis of

Ledergerber. Legdergerber teaches a covering in order to reduce scarring following the surgical implantation of the prosthesis (breast implant). However, the polymer coating used by Ledergerber is PTFE as opposed to a lactide polymer. One would be motivated to do this because lactide polymers and more particularly racemic polymers, such as the ones disclosed in Calhoun et al., are more readily degraded. Also, it has been shown that any biocompatible polymer can be utilized effectively as a coating on a plethora of implants, both non-biological as well as biological, to reduce post-surgical scarring. Since, Ledergerber teaches that a polymer coating can be applied to prosthesis, it would be obvious that this would also naturally include a prosthetic pacemaker and all other similar prosthesis. Also, it would be obvious to one skilled in the art that both a breast implant and a pacemaker would be implanted in soft tissue such that the soft tissue surrounds the implant. Calhoune et al. teaches heat joining of the micromembrane once it is wrapped around the tissue of interest. It would be obvious to one skilled in the art at the time of the invention that this technique can also be employed in relation to implants. One would be motivated to do this so as to provide a secure coating of the film on the implant.

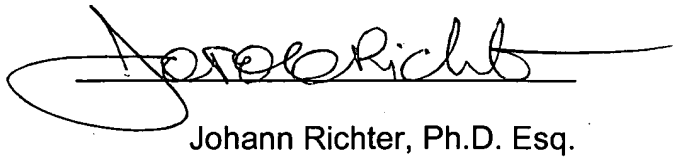
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616



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